

REMARKS

The present application relates to inbred maize line PH5TG. Claims 2-57 have been canceled. Claims 3, 11, 12, 13, 14, 17-20, 22, 28-36, 44, and 47-49 were previously canceled in the Amendment filed April 11, 2003 and claims 45 and 46 were previously canceled in the Amendment filed October 28, 2002. New claims 58-87 have been added. No new matter has been added by the present amendment. Applicant respectfully requests consideration of the following remarks.

Detailed Action

A. Claim and Specification Objections

Applicant acknowledges the rejection of claims 3, 5, 12, 13, 22, 24, 30-33, 40-44, and 47-49 under 35 U.S.C. § 112, second paragraph, as withdrawn in light of the claim amendments or cancellations. The rejection of claims 13, 17, 32, 33, 36, 41, and 43 under 35 U.S.C. §§ 102/103 are acknowledged as withdrawn, in light of the claim amendments or cancellations.

The Examiner objects to the Table A comprising SSR data inserted on page 16 of the specification at line 23 under 35 U.S.C. § 132 as new matter. Applicant objects to the Examiner's objection of new matter however in order to expedite prosecution Applicant herein cancels the above-referenced material that had been filed April 11, 2003, thus alleviating this rejection.

B. Newly Submitted Claims

Applicant acknowledges the addition of new claims 58 through 87, as specifically stated by the claims faxed by Examiner David Fox on November 15, 2002 and the new sample claim submitted by Supervisory Patent Examiner Amy Nelson via e-mail on August 7, 2003 and revised via telephone on August 25, 2003 and September 2, 2003 and per the meeting of supervisory and primary Examiners on September 11, 2003. The new claims do not add new matter as there is support for the claims in the originally filed specification. Support for the specific items noted in the claims faxed by Examiner Fox can be found within the specification for *Bacillus thuringiensis* on page 28; for imidazolinone, sulfonylurea, glyphosate, glufosinate, L-phosphinothricin, triazine, and benzonitrile on pages 31-32; for phytase on page 32; for stearyl-ACP desaturase, fructosyltransferase, levansucrase, alpha-amylase, invertase and starch

branching enzyme on page 32; and for waxy starch and increased amylose starch on pages 21 and 32. In addition, Applicant has amended the specification to clarify the deposit language. No new matter has been added by the present amendment.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 6, 25, and 50-57 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 6 and 25 are indefinite for the recitation "capable of expressing." The Examiner states it is unclear if the plant actually expresses the traits, or when or under what conditions traits are expressed.

Applicant has canceled claims 6 and 25 and added new claims 63 and 80 to include the language --having--, as suggested by the Examiner, thus alleviating this rejection.

The Examiner rejects claims 50-57 as indefinite in the recitation "PH5TG" as the name "PH5TG" is not known in the art.

Applicant traverses this rejection. The name "PH5TG" does clearly identify the claimed seeds, plants, and plant parts through the actual ATCC deposit of PH5TG in compliance under 37 C.F.R. §§ 1.801-1.809. In an effort to expedite prosecution, claims 50 and 54 have been canceled, thereby alleviating this rejection.

Claim 51 stands rejected as indefinite in the recitation "The backcross conversion PH5TG maize plant of claim 50" in line 1.

Although not acceding to the Examiner's rejection, in order to expedite prosecution Applicant has canceled claim 51, alleviating this rejection.

Claim 55 stands rejected as indefinite for the recitation "The transgenic PH5TG maize plant of claim 54" in line 1.

Although not acceding to the Examiner's rejection, in order to expedite prosecution Applicant has canceled claim 55, thereby rendering this rejection moot.

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 9, 10, 15, 16, 37-39, and 41-43 remain and claims 50-54 and 57 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record in the Office Action mailed January 13, 2003.

The Applicant traverses the rejection. Although not acceding to the Examiner's rejection, to expedite prosecution the Applicant has canceled claims 2-57, thereby rendering this rejection moot. The Applicant has added new claims 58-87, as specifically stated by the claims faxed by Examiner David Fox on November 15, 2002 and the new sample claim submitted by Supervisory Patent Examiner Amy Nelson via e-mail on August 7, 2003 and revised via telephone on August 25, 2003 and September 2, 2003 and per the meeting of supervisory and primary Examiners on September 11, 2003. The new claims do not add new matter as there is support for the claims in the originally filed specification as described *supra*.

Further, Applicant asserts one of ordinary skill in the art would know how to cross PH5TG with another maize plant. Applicant asserts it is well understood by one skilled in the art that maize is a diploid plant species thereby comprising two sets of chromosomes. The F1 hybrid seed and plant produced using PH5TG, regardless of the other maize plant used, is identifiable because it will have a single set of individual maize chromosomes coming from PH5TG. In addition, one of ordinary skill in the art would be able to run a molecular profile on PH5TG and the F1 hybrid and be able to identify the F1 hybrid as being produced from PH5TG. PH5TG is a homozygous inbred plant. When the ovule or pollen is generated from this plant, it will be haploid and will contain one complete set of chromosomes from PH5TG. Upon fertilization, the resulting zygote will receive one set of chromosomes from the parent inbred plant resulting in the diploid zygote. Inbred PH5TG has a unique set of genes present on its chromosomes and this unique set is also present in the hybrid.

As stated in the specification on page 16, lines 8-23, there are many laboratory-based techniques available for the analysis comparison and characterization of plant genotype such as Restriction Length Polymorphisms (RFLPs) and Simple Sequence Repeats (SSRs). Such techniques may be used to identify whether or not PH5TG was used to develop a hybrid. Any person of skill in the art could run a molecular profile of PH5TG based upon the deposit

Applicant has made. Therefore, it would be routine to one of ordinary skill in the art to run the profile of a hybrid plant and determine whether or not PH5TG was used as a parent.

Claim 43 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although not acceding to the Examiner's rejection, in order to expedite prosecution Applicant has canceled claim 43, thereby rendering this rejection moot.

Claims 37-39 and 50-53 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record in the Office Action mailed January 13, 2003. The Examiner states that Hunsperger *et al.*, Kraft *et al.*, and Eshed *et al.* teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype is said different plant.

Applicant respectfully traverses this rejection. Applicant has provided assurance that at least 2500 seeds of inbred maize line PH5TG have been deposited with the ATCC. In view of this assurance, the rejection under 35 U.S.C. § 112, first paragraph, should be removed. (MPEP § 2411.02). Although not acceding to the Examiner's rejection, to expedite prosecution the Applicant has canceled claims 37-39 and 50-53, thereby rendering this rejection moot. Applicant has added new claims 58-87, as disclosed *supra*. It is respectfully submitted that Applicant's claims are sufficiently described and enabled by the specification.

In addition, Applicant asserts that the introgression of mutant genes and transgenes is easily, routinely and extensively practiced by those of ordinary skill in the art. Backcrossing has been known since the 1920's and, because of its predictability, is the method preferred by commercial plant breeders to introduce transgenes into already developed and tested material. An example of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion lines are easily developed without undue experimentation.

Further, Applicant would like to reiterate that a patent application "need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986); MPEP § 601.

Applicant also respectfully disagrees with the Examiner as to what is taught by Hunsperger *et al.* Hunsperger *et al.* merely teaches that a gene that results in dwarfism of a petunia plant can be incorporated into other genetic backgrounds of the petunia species (See column 2, line 67 to column 3, lines 1-4). Hunsperger *et al.* merely discusses that the level of the expression of that gene differed in petunia plants of different genetic backgrounds. Hunsperger *et al.* succeeded in incorporating the gene into petunia plants of different genetic backgrounds. In fact, the USPTO in Hunsperger *et al.* allowed claims to any petunia plant comprising genes for dwarfism. Therefore, Hunsperger *et al.* supports the fact that one can introgress a specific trait into a recurrent parent through backcross conversion. Applicant's specification provides ample disclosure of starting materials such as, maize inbred line PH5TG, a discussion of traditional breeding methods, and examples of transgenes and naturally occurring genes that may be used in such methods. Hallauer *et al.* (1988) on page 472, submitted in the Information Disclosure Statement, states that, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." The teaching of Hallauer *et al.* relates specifically to corn breeding and corn inbred line development.

The Examiner goes on to state that, "Kraft *et al.* teaches that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotypic specific and loci-dependent in nature" (page 323, column 1, lines 7-15). Applicant disagrees that the article states such points. Kraft *et al.* makes no mention of a plant comprising a single gene conversion or the use of backcrossing. Further, Kraft *et al.* relates to linkage disequilibrium and fingerprinting in sugar beet, a crop other than maize. Kraft *et al.* states, on page 326, first column, "The generality of our results for other crop species needs to be investigated."

It is understood by those of skill in the art that backcross conversions are routinely produced and do not represent a substantial change to a variety. The World Seed Organization, on its web site, writes, "The concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple backcrossing and to fill the gap between Plant Breeder's Rights and patents." As determined by the

UPOV Convention, "essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

The Examiner goes on to state that, "Eshed *et al.* teaches that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in genetically complex and less than additive fashion" (page 1815, column 1, line 1 to page 1816, column 1, line 1). The Applicant would like to point out on page 1816, column 1; lines 1-5 of the Eshed *et al.* article it states, "Recent studies that detected epistasis of selected QTL in *Drosophila* (Long *et al.* 1995), soybean (Lark *et al.* 1995) and maize (Doebley *et al.* 1995; Cockerham and Zeng 1996) did not show a less-than-additive trend." Emphasis added. The Applicant also adds that transferring a qualitative trait does not require undue experimentation. Please note Hallauer *et al.* (1988) on page 472, submitted in the Information Disclosure Statement, which states, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." In newly submitted claims 58-87, the genes transferred into PH5TG are now limited to the traits of disease resistance, insect resistance, herbicide resistance, male sterility, waxy starch, and a nucleic acid molecule that encodes an enzyme that modifies fatty acid metabolism, phytic acid metabolism or carbohydrate metabolism. Applicant respectfully requests the Examiner to withdraw this rejection. For the reasons aforementioned, it is respectfully submitted that Applicant's claims are sufficiently described and enabled by the specification.

Claim 54 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner states the claim does not reasonably provide enablement for the claimed method with all transgenes.

Although not acceding to the Examiner's rejection, in order to expedite prosecution Applicant has canceled claim 54, thereby rendering this rejection moot.

In light of the above amendments and remarks, Applicant respectfully requests withdrawal of the rejections to claims 9, 10, 15, 16, 37-39, 41-43, 50-54, and 57 under 35 U.S.C. § 112, first paragraph.

Summary

Applicant acknowledges that claims 1, 2, 4, 5, 7, 8, 21, 23, 24, 26, 27, and 40 are allowed.

Applicant has amended the claims as suggested by Examiner David Fox and Supervisory Patent Examiner Amy Nelson as allowable. Applicant submits the claims place the application in condition for allowance and comply with all requirements of form set forth in previous office actions.

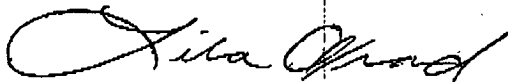
Conclusion

In conclusion, Applicant submits in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



Lila A. T. Akrad, Reg. No. 52,550
McKee, Voorhees & Sease, P.L.C.
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309-2721
Phone No: (515) 288-3667
Fax No: (515) 288-1338
CUSTOMER NO: 27142

Attorneys of Record

**RECEIVED
CENTRAL FAX CENTER**

OCT 01 2003

OFFICIAL

- bja -